

**STATE OF CALIFORNIA  
OFFICE OF ADMINISTRATIVE LAW**

In re:	)	
	)	
	)	DECISION OF DISAPPROVAL
	)	OF REGULATORY ACTION
DENTAL BOARD OF	)	
OF CALIFORNIA	)	(Gov. Code, sec. 11349.3)
	)	
REGULATORY ACTION:	)	
Title 16,	)	
California Code of Regulations	)	OAL File No. 07-0511-01 S
	)	
ADOPT: 1044.4	)	
AMEND: 1044, 1044.1, 1044.2,	)	
1044.3, 1044.5	)	
_____	)	

**DECISION SUMMARY**

This action proposes regulations to implement AB 1386 (Chap. 539, Stats. 2005) by establishing the procedure whereby dentists may obtain a certificate from the Dental Board of California qualifying them to administer oral conscious sedation (OCS) to adult patients.

On June 25, 2007, the Office of Administrative Law (“OAL”) notified the Dental Board of California (“DBOC”) of the disapproval of the above-referenced regulatory action. OAL disapproved the regulations for the following reasons: (1) failure to comply with the “Clarity” standard of Government Code section 11349.1, (2) failure to comply with the “Necessity” standard of Government Code section 11349.1, (3) failure to summarize and/or adequately respond to each comment made regarding the proposed action, and (4) failure to comply with APA procedural requirements.

**DISCUSSION**

Regulations adopted by DBOC must generally be adopted pursuant to the rulemaking provisions of the Administrative Procedure Act (the “APA;” Gov. Code, secs. 11340 through 11361). Any regulatory action a state agency adopts through the exercise of quasi-legislative power delegated to the agency by statute is subject to the requirements of the APA, unless a statute expressly exempts or excludes the act from compliance with the APA. (See Gov. Code, sec. 11346.) No exemption or exclusion applies to the regulatory action here under review. Consequently, before these regulations may become effective, the regulations and the rulemaking record must be

reviewed by OAL for compliance with the procedural requirements and the substantive standards of the APA, in accordance with Government Code section 11349.1.

### CLARITY

OAL must review regulations for compliance with the substantive standards of the APA, including the “Clarity” standard, as required by Government Code section 11349.1. Government Code section 11349, subdivision (c), defines “Clarity” as meaning “written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them.”

The “Clarity” standard is further defined in section 16 of Title 1 of the California Code of Regulations (“CCR”), OAL’s regulation on “Clarity,” which provides the following:

“In examining a regulation for compliance with the ‘clarity’ requirement of Government Code section 11349.1, OAL shall apply the following standards and presumptions:

(a) A regulation shall be presumed not to comply with the ‘clarity’ standard if any of the following conditions exists:

- (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
- (2) the language of the regulation conflicts with the agency’s description of the effect of the regulation; or
- (3) the regulation uses terms which do not have meanings generally familiar to those ‘directly affected’ by the regulation, and those terms are defined neither in the regulation nor in the governing statute; or
- (4) the regulation uses language incorrectly. This includes, but is not limited to, incorrect spelling, grammar or punctuation; or
- (5) the regulation presents information in a format that is not readily understandable by persons ‘directly affected;’ or
- (6) the regulation does not use citation styles which clearly identify published material cited in the regulation.

(b) Persons shall be presumed to be ‘directly affected’ if they:

- (1) are legally required to comply with the regulation; or
- (2) are legally required to enforce the regulation; or
- (3) derive from the enforcement of the regulation a benefit that is not common to the public in general; or
- (4) incur from the enforcement of the regulation a detriment that is not common to the public in general.”

**1. Form OCS-3 Not Identified.** This action proposes regulations to implement AB 1306 (Chap. 539, Stats. 2005) by establishing the procedure whereby dentists may obtain a certificate from the DBOC qualifying them to administer oral conscious sedation (OCS) to adult patients. AB 1306 makes such certificates mandatory effective January 1, 2006. Existing regulations only cover requirements for qualifying to administer OCS to minors. These proposed regulations add the adult OCS requirements into the existing minor OCS regulations by specifying within the

minor OCS regulations the required training and educational requirements for the adult OCS certificate, the adult OCS course approval procedure, and the mechanism to demonstrate 10 pre – December 31, 2005 adult OCS procedures in order to be “grandfathered” as an adult OCS dentist under Business and Professions Code section 1647.20(d). The initial regulation text included no new or updated forms for use by dentists applying for an adult OCS certificate. However, on March 6, 2007 the DBOC noticed 15-day changes to the proposed regulation text which included the adoption of three new forms:

OCS-3 (Rev. 03/07) “Application for Adult Oral Conscious Sedation Certificate”

OCS-6 (Rev. 03/07) “Application for Course Approval for Either Adult or Minor Oral Conscious Sedation”

OCS-4 (Rev. 03/07) “Documentation of Adult Oral Conscious Sedation Cases”

Forms OCS-6 and OCS-4 are specifically identified, required to be used, and expressly incorporated by reference in these proposed regulations. In contrast, form OCS-3, the application for the adult OCS certificate, is not identified, incorporated by reference, (even though the final statement of reasons states that it was “incorporated by reference”) or specifically required to be used by the applicant in order to apply for an adult OCS certificate anywhere in these regulations. Failure to do so in the regulation text is a presumed Clarity violation under Title 1 CCR section 16(a)(2) and (a)(5).

**2. Form OCS-1 Not Adopted.** DBOC’s existing regulations governing minor OSC do not specify any required form or application procedure for obtaining a minor OCS certificate. Proposed section 1044 (c) specifically refers to and distinguishes between adult and minor OCS certificates. Section 1044(c) states:

“(c) ‘Age-appropriate’ means under 13 years of age for the oral conscious sedation certificate for minor patients and 13 years or older for the oral conscious sedation certificate for adult patients.”

By adopting new form OCS-3 (Rev. 03/07) “Application for Adult Oral Conscious Sedation Certificate”, DBOC creates a Clarity issue regarding what application form a dentist applying for a minor OCS certificate must use in order to become licensed. This clarity issue has apparently been at least partially resolved by DBOC’s use of form OCS-1 (Rev. 1/05) “Application for Oral Conscious Sedation for Minors Certificate” which currently appears on DBOC’s website. Form OCS-1 is not part of this rulemaking and does not appear to have been adopted pursuant to the APA. DBOC should adopt form OCS-1 as part of this rulemaking in order to resolve the Clarity issue created by the adoption of the adult OCS application form without specifying a similar application form for minor OCS certification.

### **NECESSITY**

Government Code section 11349.1, subdivision (a)(1) requires OAL to review all regulations for compliance with the “Necessity” standard. Government Code section 11349, subdivision (a) defines “Necessity” to mean that:

“ . . . the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard evidence includes, but is not limited to facts, studies, and expert opinion.”

Section 10, subdivision (b) of Title 1 of the CCR provides that in order to meet the “Necessity” standard the rulemaking record must include:

“(1) A statement of the specific purpose of each adoption, amendment, or repeal; and

(2) information explaining why each provision of the adopted regulation is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information. An ‘expert’ within the meaning of this section is a person who possesses special skill or knowledge by reason of study or experience which is relevant to the regulation in question.”

On March 6, 2007, the DBOC noticed 15-day changes to the proposed regulation text which included the adoption of three new forms:

OCS-3 (Rev. 03/07) “Application for Adult Oral Conscious Sedation Certificate”

OCS-6 (Rev, 03/07) “Application for Course Approval for Either Adult or Minor Oral Conscious Sedation”

OCS-4 (Rev. 03/07) “Documentation of Adult Oral Conscious Sedation Cases”

OCS-3 is two pages in length, OCS-6 is one page in length, and OCS-4 is three pages in length. The final statement of reasons contains the following discussion of the 15-day text changes and adoption of the three new forms:

“Updated Information

The initial Statement of Reasons is included in the file. The information contained therein is updated as follows:

**Current regulations include OCS-5 (rev 10/99) and OCS-3 (rev 10/99) which should be removed and replaced by OCS-6 (03/07) , OCS-3 (03/07) and OCS-04 (Rev 03/07), incorporated by reference.**

A typographical error in Section 1044(d) referencing the FDA as the ‘Federal Drug Agency’ has been corrected to ‘Food and Drug Agency.’” [Emphasis added in bold].

This discussion is simply a description of the adoption of the three forms and provides no rationale as required by Title 1 CCR section 10(b)(2) for the specific content of each form or the other substantive changes made to the regulation text in the 15-day notice. Of particular importance is OCS-3's new nonrefundable application fee of \$200 which must be enclosed with the application for an adult oral conscious sedation certificate. The only reference to this fee in any part of the regulation text is this entry on the top left of OCS-3:

“Non Refundable FEE: \$200 (must be enclosed with application) Section 1021  
Title 16 California Code of Regulations.”<sup>1</sup>

The rulemaking file is devoid of any discussion of, let alone substantial evidence supporting, the amount of this fee or its compliance with the requirements of Business and Professions Code section 1647.23 which provides:

“1647.23. **The fee for an application for initial certification or renewal under this article shall not exceed the amount necessary to cover administration and enforcement costs incurred by the board in carrying out this article.** The listed fee may be prorated based upon the date of the renewal of the dentist's license or permit.” [Emphasis added in bold].

In order to satisfy the Necessity standard, DBOC must provide data showing that the \$200 fee does not exceed the amount necessary to cover administration and enforcement costs incurred by the board in carrying out this article. And, any data developed by the DBOC to support the \$200 application fee for adult oral OCS must be properly noticed for public comment prior to resubmittal of the rulemaking action. Other substantive content on the three forms and changes to the regulation text made during the 15-day process must similarly be supported by facts, studies or expert opinion articulating DBOC's rationale for each change.

## SUMMARY AND RESPONSE TO PUBLIC COMMENTS

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<sup>1</sup> Title 16 CCR section 1021 is DBOC's consolidated fee regulation. Subsection (s) provides that the fee for “oral conscious sedation” is \$200:

“ (s) General anesthesia or conscious sedation permit or oral conscious sedation certificate.....\$200”

Subsection (s) does not provides substantial evidence for DBOC's setting the adult OCS fee as \$200 on new form OCS-3 because 1) subsection (s) does not specify adult OCS as being included in the fee and 2) the \$200 fee in subsection (s) was adopted prior to the legislature granting DBOC the authority to certify dentists as qualified to perform adult OCS pursuant to AB 1386. AB 1386 became effective on January 1, 2006. The \$200 fee in subsection (s) for “oral conscious sedation” was adopted by the DBOC on May 15, 2000.

Government Code section 11346.9, subdivision (a), provides that an agency proposing regulations shall prepare and submit to OAL a “final statement of reasons.” One of the required contents of a final statement of reasons is a summary and response to public comments. Specifically, Government Code section 11346.9, subdivision (a)(3), requires that the final statement of reasons include:

“A summary of each objection or recommendation made regarding the specific adoption, amendment, or repeal proposed, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change. This requirement applies only to objections or recommendations specifically directed at the agency’s proposed action or to the procedures followed by the agency in proposing or adopting the action. . . .”

DBOC received a significant number of written comments and oral testimony regarding this action. At least two of DBOC’s responses to comments are inadequate because they fail to address the commenter’s relevant objection or recommendation regarding this regulatory action or the rulemaking procedures followed.

**1. Comment by Paul Coleman, DMD.** DBOC summarized and responded to a comment by Paul Coleman, DMD, as follows:

“(6) A written comment from Paul Coleman, DMD, recommended following the guidelines outlined by the American Dental Association, and spoke against any guidelines that would set up barriers for the dental phobic as being detrimental to the dental health of the citizens of California. The board considered this comment and determined that it contained no clear recommendations.”

The response in the last sentence is inadequate because it fails to address Dr. Coleman’s recommendation that DBOC follow ADA guidelines for adult OCS instead of DBOC’s proposed regulations.

**2. Comment by Daniels C. Thirlwall, DMD.** DBOC summarized and responded to a comment by Daniels C. Thirlwall, DMD, as follows:

“(9) A written comment from Dr. Daniels C. Thirlwall, DMD encouraged the board to ‘listen to the representatives from the DOCS organization and adopt their criteria as California [sic] standard of care.’ The board considered the DOCS protocols and decided not to reduce the existing requirements for 25 hours of education including a clinical component utilizing at least one age-appropriate patient.”

The response is inadequate because DBOC doesn’t articulate reason(s) why the DBOC chose not to reduce the 25 hours of education and the one live patient clinical component

and adopt the DOCS criteria instead. The response is simply a conclusion by the DBOC to the contrary.

### INCORRECT APA PROCEDURES

**1. Incomplete Updated Informative Digest.** Government Code section 11347.3(b)(2) requires every rulemaking file to contain an updated informative digest. The updated informative digest in this file is inaccurate and incomplete. The updated informative digest included in Tab I states:

#### “UPDATED INFORMATIVE DIGEST

No changes have been made which would warrant a change to the Informative Digest contained in the original Notice of Section 1044.”

This statement is inaccurate because DBOC made numerous substantive changes to the regulation text as well as adopted the three forms discussed above by way of the March 6, 2007 15-day notice after preparation of the initial statement of reason. The updated informative digest should be updated to briefly discuss the substantive changes made by the 15-day notice and the effect on the proposed regulations.

**2. Incorporation By Reference Not in Compliance.** The rulemaking file fails to comply with the incorporation by reference requirements of Title 1 CCR sections 20 (c)(1), (2), (4) and (5). Section 20(c) states:

“(c) An agency may ‘incorporate by reference’ only if the following conditions are met:

(1) The agency demonstrates in the final statement of reasons that it would be cumbersome, unduly expensive, or otherwise impractical to publish the document in the California Code of Regulations.

(2) The agency demonstrates in the final statement of reasons that the document was made available upon request directly from the agency, or was reasonably available to the affected public from a commonly known or specified source. In cases where the document was not available from a commonly known source and could not be obtained from the agency, the regulation shall specify how a copy of the document may be obtained.

(3) The informative digest in the notice of proposed action clearly identifies the document to be incorporated by title and date of publication or issuance. If, in accordance with Government Code section 11346.8(c), the agency changes the originally proposed regulatory action or informative digest to include the incorporation of a document by reference, the document shall be clearly identified by title and date of publication or issuance in the notice required by section 44 of these regulations.

(4) The regulation text states that the document is incorporated by reference and identifies the document by title and date of publication or issuance. Where an

authorizing California statute or other applicable law requires the adoption or enforcement of the incorporated provisions of the document as well as any subsequent amendments thereto, no specific date is required.

(5) The regulation text specifies which portions of the document are being incorporated by reference.”

**3. Text Not in Compliance.** The rulemaking text fails to comply with the requirements of Title 1 CCR section 8 because the newly adopted forms OCS-3, OCS-6, OCS-4, and repealed forms OCS-5 and the previous version of OCS-3 are not properly shown in underline/strikeout or labeled as “repeal” or “adopt”. In addition, copies of the forms are not attached to the regulation text for filing with the Secretary of State as required by Government Code section 11343(c).

### **ADDITIONAL CORRECTIONS**

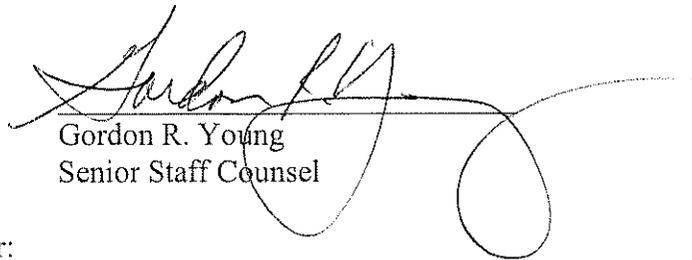
While not reasons for disapproval, DBOC should correct the following items prior to resubmittal:

1. The DBOC should delete the “Z” notice file number from block B.1b. of the Form 400 used for listing all previous related OAL regulatory action number(s).
2. There are several other minor punctuation or formatting errors in the regulation text. OAL will consult with DBOC and coordinate correction of these errors prior to resubmittal.

### **CONCLUSION**

OAL disapproved this regulatory action for the reasons set forth above. If you have any questions, please contact me at (916) 323-8916.

**Date:** July 2, 2007

  
Gordon R. Young  
Senior Staff Counsel

For:

SUSAN LAPSLEY  
Director

Original: Robert Hedrick, Executive Officer

Cc: Donna Kantner